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Probiotic (VSL#3) for Gulf War Illness.

PRINCIPAL INVESTIGATOR:

Ashok Tuteja, M.D. M.P.H.

CONTRACTING ORGANIZATION:

Western Institute for Biomedical Research

Salt Lake City, UT 84148

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14. ABSTRACT The overall objective of the study is to determine whether probiotic Visbiome™ will improve 1) Intestinal symptoms of Irritable Bowel Syndrome and 2) Non-intestinal symptoms (fatigue, joint pain, insomnia, general stiffness and headache) associated with IBS. All of these symptoms are part of the Gulf War illness. We screened our first participant in September 2013. Overall we have screened 73 and enrolled 34 Gulf War Veterans so far. Our efforts are ongoing to recruit more Gulf War veterans. The first set of stool samples have been sent to Lawrence Berkeley Laboratory for microbiota analysis.					
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## Table of Contents

	<u>Page</u>
Introduction.....	1
Body.....	1
Key Research Accomplishments.....	2
Reportable Outcomes.....	3
Conclusion.....	4
References.....	5
Appendices.....	6

**Introduction:**

Gastroenteritis plays a major role in changing intestinal microflora. More than one third of Gulf War (GW) veterans report gastroenteritis during deployment and it is a risk factor for development of irritable bowel syndrome (IBS) after deployment. We also demonstrated that there is a strong association between IBS and extra-intestinal disorders (e.g. fatigue, joint pains, insomnia, generalized stiffness, and headache). This would suggest that IBS as well as extra-intestinal disorders in GW veterans have a unifying etiology. There is scientific evidence that probiotics by restoring normal gut flora improve symptoms of IBS. Probiotics have also been shown to improve arthritis and fatigue by changing fecal flora. This is the basis for our present protocol to study the effect of probiotics on GW illness.

**Body:**

The exclusive distributor of the probiotic in United States, will market and sell the probiotic VSL#3 under a different trade name Visbiome.<sup>TM</sup> We will be using Visbiome <sup>TM</sup> as our study drug which has the same formulation as VSL#3

1. The University of Utah IRB and VA Research Office approved our amendment for change in the name of the Probiotic.
2. The FDA has no objection in the amendment for change in the name of the Probiotic.
3. The Department of Defense HRPO office approved our amendment for change in name of the probiotic.

During the last on year the following goals were accomplished:

- We have screened 72 GW veterans and enrolled 34 from the beginning of the study. Of the 34 veterans enrolled in the study, 28 have completed the study. Three veterans are on medication and nine veterans are in the screening phase. Two participants have been excluded from the study due to co-morbid conditions affecting the study assessment.
- The first set of stool samples have been sent to the Lawrence Berkeley laboratory for microbiota analysis.
- We have received the list of Gulf War Veterans in the Salt Lake City are from the Defense Manpower Database. We have send recruitment letters to these veterans informing them about the study.

**Key Research Accomplishments.....**

- We have recruited 34 Gulf War Veterans and continue to make progress in recruiting more Veterans.

**Reportable Outcomes.....**

Nil.

**Conclusion:**

Study is ongoing at a good pace as we planned. We continue our recruitment efforts to increase our study enrollment. First set of stool and blood samples will be analyzed.

**References.....**

Nil.



**Appendices.....**

Nil.

